

REMARKS

The application has been amended and is believed to be in condition for allowance.

Formal Matters

The previously pending claims have been cancelled and replaced with a new set, based on the previous claims and revised as noted below.

Previous claim 17 covering the medical device has been removed.

Responsive to the abstract objection, the Abstract has been amended to include antecedent basis for previous claims 20, 21 and 22.

Responsive to the declaration objection, a replacement combined Declaration and Power of Attorney is attached.

The replacement claims have been drafted taking into account the formal criticisms of the Official Action, e.g., terms "preferably", "such as", "optionally suitable additives", and "based on a compound" have been removed, and the term "together" is used in new claim 31 (prior claim 1) in order to clarify that the specified amount encompasses both the CA and C12A7 phases. Written support is found on page 11, last line of the specification. If this recitation is not acceptable, applicants would appreciate a suggestion as to an acceptable alternative recitation and would also appreciate the claim being interpreted as indicated.

The new claims have been drafted to be in proper Markush terminology.

The terms "powder/particle raw material" of previous claim 12 has been changed to "powdered material". The term "powdered" has been inserted into claim 31.

The features in previous claim 13 have been inserted into new claim 31.

In view of the above, the newly presented claims are believed proper as to form and therefore withdrawal of the indefiniteness rejection is solicited.

As claim 17 has been cancelled, the 112, first paragraph, rejection is moot.

Claims 1-22 were provisionally rejected under obviousness-type double patenting over application 10/673,250.

Note that the previous copending application was 10/739,266 and further that the application has been abandoned. Therefore, withdrawal of the obviousness-type double patenting rejection is solicited.

#### Substantive Rejections

Claims 1, 5, 8, 9 and 11-22 were rejected as obvious over KAWAHARA et al. 4,652,593.

Claims 3, 4, 6, 7 and 10 were rejected as obvious over KAWAHARA et al. in view of SE 010441-1 ("SE 441").

Claims 1, 2, 5-8 and 12-22 were rejected as obvious over SE 463,493 ("SE 493").

Claims 3, 4, and 9-11 were rejected as obvious over SE 493 in view of SE 441.

Claims 1-22 were rejected as obvious over SE 441.

Why the claims are patentable.

New claim 31 recites lower limits for the CA2.

The lower limit of CA2 has been set to 0 vol%. Support for this amendment is found on page 11, lines 34-35.

Pages 10-12 shows that CA2 is used when slow curing, i.e. little temperature generation is required (see e.g. page 11, lines 29-30), thus making CA2 particularly useful at the lower end of the temperature interval 30-150°C as achieved during the curing of the present invention material.

New claim 69 recites the preferred upper C3A value. C3A is primarily used for achieving high temperatures (see e.g. page 11, lines 9-10), i.e. temperatures at the upper end of the temperature interval 30-150°C. The indicated preferred range for the C3A phase is less than 3 vol%.

New claim 70, as to the C3A phase, recites the lower limit has an effective amount and an upper limit of less than 10 vol%. On page 12, lines 1-2, it is stated that a smaller part of C3A is desired in order to accelerate or trigger the curing. A person skilled in the art could easily find out what exact percentage of C3A that is desirable in order to generate a certain temperature for an intended use. C3A is primarily used for achieving high temperatures (see e.g. page 11, lines 9-10), i.e.

temperatures at the upper end of the temperature interval 30-150°C.

The generation of heat when curing a material is previously known from the prior art. In most cases it is a feature of the hardening process that is undesirable, in particular for dental applications. However, no one has taught that generated heat could be used for the therapeutic purposes mentioned in the present invention (cancer treatment, pain relief, vascular treatment, bone restoration and activation of drugs, see page 4, lines 30-31) in a controlled fashion.

Being able to control the temperature generation is something that is very important in order to control damage to surrounding tissues. Neither the cited references, nor any other prior art documents acknowledge the use of any generated temperature for the therapeutic purposes according to the present invention, or provides any means to control such a temperature increase.

Another important feature of the present invention, in particular for orthopaedic applications, is the high compressive strength (at least 100 MPa) exhibited by the material according to the present invention. In orthopaedic applications a compressive/crushing strength of 100 MPa is required. When a material curing in the body generates a high temperature and kill malignant tissue, said loss of tissue creates a lack of support. In such a case, the inserted cured material must provide said

support. For example, in the case of curing a skeletal cancer, the material inserted as an implant enables early load-bearing. The material according to the present invention provides the support needed.

#### Applied References

KAWAHARA relates to ceramic materials used for dental applications (see column 1, lines 5-10). KAWAHARA does not mention that their materials generate high temperatures, or that they know how to control the temperature generation. Moreover, for dental applications, the generation of high temperatures during hardening would be highly disadvantageous since it might create cracks and destroy surrounding tissue.

KAWAHARA does mention that the ceramic materials could include the same phases as described in the present invention. However, KAWAHARA does not specify any suitable ranges for such phases. The only information presented is a percentage for the calcium oxide (see beginning at column 2, line 56). Said information would not be sufficient for a person skilled in the art to control such a temperature generation.

The KAWAHARA material is a low-strength material with a compressive strength that does not exceed 70MPa (see Example 1), which is too low for orthopaedic applications.

SE-463,493 (belonging to the assignee, Doxa AB) relates to ceramic materials for dental and orthopaedic applications. SE-463,493 also mentions that the CA-material may comprise different

phases, some of which correspond to the phases of the present invention material, but no suitable ranges for those phases are specified (see page 5, first paragraph).

Moreover, there is no mention of any temperature generation or it being associated with any particular phase. Moreover, there is nothing in said document that teaches or suggests any modifications of the disclosed ceramic materials such that they would generate higher temperatures during curing.

SE-463,493 discloses various compressive strength values. Examples 5, 6 and 10 disclose values of 210-270 MPa. These values are achieved for highly compacted raw bodies, and the temperature increase is low - less than 1 °C in a body cavity. The reason is the composition of the raw material Secar 71 (approximately 50/50 for the phases CA and CA2) and inert additives, as well as the relatively low amounts of material used, i.e. < 1 g. Thus, the ceramic material used in SE-463,493 does not have the heat-generating properties required for the therapeutic applications disclosed in the present invention.

SE-010441-1 (now belonging to the assignee, Doxa AB after the merger with Cerbio AB) discloses a ceramic material intended for dental and orthopaedic applications that, like the other cited documents, mentions that the ceramic material could include the same phases as described in the present invention. Like the others, SE-010441-1 does not specify any suitable ranges for such phases.

SE-010441-1 acknowledges the generation of heat during curing and presents this as a problem. SE-010441-1 limits the heat generation to less than 40°C by using inert fillers such as ternary oxides. The reason is the disclosed phase composition and the amount of inert additives and low concentration of accelerators used. The temperature increase cannot be controlled unless the composition is as specified in claims 31-33 of the present invention, and the concentration of the processing aids, i.e. accelerators and retarders are as specified in the claims. The inventors of the present invention, which were also involved in the filing of SE-010441-1, were at the time capable of keeping the heat generation during hardening below 40°C by using inert fillers not generating any heat.

However, at the filing date of SE-010441-1, those inventors did not possess the knowledge of controlling the temperature within the temperature range of 30-150°C with undiminished strength properties. This is the reason why no information regarding any temperature control is described or hinted in said document.

All of the phases in claim 31 (according to present invention) are necessary in order to achieve a controlled temperature generation of 30-150°C and a sufficiently high compression strength that makes it suitable for the therapeutic purposes specified in the application.

Thus, from the above, it is believed clear that none of the references, taken either individually or in any reasonable combination, teaches or suggests the recited features of the present invention. Accordingly, reconsideration and allowance of all the claims are respectfully requested.

Applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

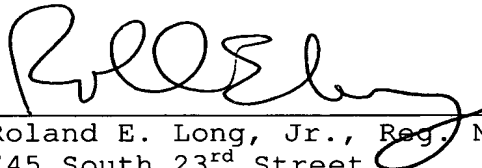
Should there be any matters which can be resolved by telephone, it is requested that the undersigned attorney be contacted in order to discuss any needed items.

Please charge the fee of \$500 for ten extra dependent claims added herewith to Deposit Account No. 25-0120.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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REL/lrs



**APPENDIX:**

The Appendix includes the following items:

- amended Abstract of the Disclosure
- signed and dated Combined Declaration and Power of Attorney